Individual Safety Report
3229681-5-00-01

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Pfizer

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"+" indicates item continued

Approved by FDA on 12/02/93

Mfr report # 9811444

UF/Dist report #

FDA Use Only

A. Patient Information

1. Patient Identifier	2. Age at time of event: 59 YRS or Date of Birth:	3. Sex	4. Weight
[redacted] in confidence		☒ Female ☐ Male	UNK lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event: 01/28/98 (mo/day/yr)

4. Date of this report: 03/12/99 (mo/day/yr)

5. Describe event or problem

A PHYSICIAN REPORTED THAT A PATIENT TREATED WITH DIFLUCAN (FLUCONAZOLE) AND TYLENOL (ACETAMINOPHEN) FOR THRUSH EXPERIENCED JAUNDICE ACCOMPANIED BY ELEVATED LIVER ENZYMES.
ADDITIONAL INFORMATION RECEIVED FROM THIS PHYSICIAN REPORTS THAT A PATIENT WHO HAD DYSURIA AND ORAL THRUSH WAS GIVEN BACTERIM DS(SULFAMETHAZOLE-TRIMETHOPRIM) AND FLUCONAZOLE DEVELOPED JAUNDICE ON 28JAN98 AND WAS ADMITTED TO THE HOSPITAL FOR 24 HOURS,UNABLE TO WORK FOR 4 WEEKS. PATIENT ADMITTED TO TAKING EXTRA STRENGTH ACETAMINOPHEN 4 TO 6 TIMES DAILY FOR A HEADACHE.
PATIENT ALSO HAS ELEVATIONS OF ALKALINE PHOSPHATASE, SERUM GLUTANIC OXALOACETIC TRANSAMINASE AND SERUM GLUTAMIC PYRUVIC TRANSAMINASE AND TOTAL BILIRUBIN. THE PATIENT ALSO HAD A LOW ALBUMIN

6. Relevant tests/laboratory data, including dates

TOTAL IRON - 184	ALBUMIN 2.8
TOTAL IRON BINDING CAPACITY - 329	ALKALINE PHOSPHATASE 206
FERRITIN >1000	BUN 12
SODIUM - 132	CREATININE 0.7
TOTAL BILIRUBIN	7.4
SGOT	129

+

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)

ASTHMA
-SINCE 1978
ALLERGIC RHINITIS

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- # 1 DIFLUCAN TABLETS
- # 2 TYLENOL

2. Dose, frequency & route used
- # 1 UNKNOWN
- # 2 UNKNOWN

3. Therapy dates (if unknown, give duration) from/to (or best estimates)
- # 1 01/22/98 - 01/27/98
- # 2 01/22/98 - 01/27/98

4. Diagnosis for use (indications)
- # 1 ORAL THRUSH
- # 2 HEADACHE

5. Event abated after use stopped or dose reduced
- # 1 ☒ yes ☐ no ☐ doesn't apply
- # 2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- # 1 UNKNOWN
- # 2 UNKNOWN

7. Exp. date (if known)
- # 1 UNKNOWN
- # 2 UNKNOWN

8. Event reappeared after reintroduction
- # 1 ☐ yes ☐ no ☒ doesn't apply
- # 2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)

N/A

10. Concomitant medical products and therapy dates (exclude treatment of event)

BACTRIM DS	01/22/98 - 01/23/98
BIAXIN	UNKNOWN
SEREVENT	UNKNOWN - PRESENT
AEROBID	UNKNOWN - PRESENT
RHINOCORT	UNKNOWN - PRESENT
ALBUTEROL	UNKNOWN - PRESENT

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

PFIZER REGULATORY SAFETY
PFIZER PHARMACEUTICALS
235 EAST 42 STREET
NEW YORK, N.Y. 10017
U.S.A

2. Phone number: 212-573-3129

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 04/22/98

5. (A) NDA # NDA #19-949 IND # PLA #
- pre-1938 ☐ yes
- OTC product ☐ yes

6. If IND, protocol #: N/A

7. Type of report (check all that apply)
- ☐ 5-day ☐ 15-day
- ☐ 10-Day ☒ periodic
- ☒ initial ☐ follow-up # ____

8. Adverse event term(s)

JAUNDICE
LIVER FUNCTION TESTS ABNORMAL
HYPOPROTEINEMIA

9. Mfr. report number: 9811444

RECEIVED
MAR 30 1999

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: PULMONARY MEDICINE

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

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Fascimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9811444

B6. RELEVANT TESTS/LAB. DATA - Continued

SGPT	71
HEP A IGM	NEGATIVE
HEPBSAG	NEGATIVE
BCAB	NEGATIVE
HEP C AB	NEGATIVE
ANA	NEGATIVE
AMA	NEGATIVE

ULTRASOUND OF ABDOMEN - SLIGHTLY ENLARGED LIVER WITH MULITPLE CYSTS, CONTRACTED GALL BLADDER, NO STONES OR OBSTRUCTION.